



USDA Foreign Agricultural Service

GAIN Report

Global Agriculture Information Network

Template Version 2.09

Voluntary Report - Public distribution

Date: 10/23/2008

GAIN Report Number: JA8065

Japan

Food and Agricultural Import Regulations and Standards

MRL changes - Flonicamid, Mandipropamid, Valnemulin & Glycyrrhizic acid

2008

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Report Highlights:

On October 16, 2008, Government of Japan announced proposed changes to the MRLs for two pesticides (Flonicamid and Mandipropamid) and two veterinary drug (Valnemulin and Glycyrrhizic acid) in food. The comment period will close on October 30, 2008. After the domestic comment period closes, MHLW will then notify these proposed changes to the WTO/SPS committee.

Includes PSD Changes: No
Includes Trade Matrix: No
Trade Report
Tokyo [JA1]
[JA]

Summary

The Japanese Ministry of Health Labour and Welfare (MHLW) announced on June October 16, 2008, proposed changes to the MRLs for two pesticides (Flonicamid and Mandipropamid) and two veterinary drug (Valnemulin and Glycyrrhizic acid). The period for sending comments on these changes ends October 30, 2008. If you have comments it is best to send directly to MHLW as soon as possible. However, MHLW will also notify these proposed changes to the WTO/SPS committee, which will provide another chance for public comments to be submitted on this subject. Then after the closing of a the comment period in the WTO, a final report will be made based on the conclusions of a session of the Pharmaceutical Affairs and Food Sanitation Council slated to be held at a later date; this will constitute the final decision.

The comments can be either Japanese or English.

If you have comments, please send them directly to the Japanese Government at:

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Department of Food Safety,
Pharmaceutical and Food Safety Bureau,
Ministry of Health, Labour and Welfare
1-2-2, Chiyoda-ku, Kasumigaseki, Tokyo, 100-
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Please also consider copying the U.S. Embassy, Tokyo at agtokyo@usda.gov on your comments in order for them to be considered as part of the official U.S. Government comments to the WTO.

Establishment of Maximum Residue Limits for Pesticides (Flonicamid and Mandipropamid) in Food

Purpose and Background

The Ministry of Health, Labour and Welfare (MHLW) is going to develop the compositional specification for food. Under the provisions of Article 11, Paragraph 1 of the Food Sanitation Law, the Minister of Health, Labour, and Welfare is authorized to establish residue standards (maximum residue limits: MRLs) for pesticides, feed additives, and veterinary drugs (hereafter referred to as just "agricultural chemicals") that may remain in foods. Any food for which standards are established pursuant to the provisions is not permitted to be marketed in Japan unless such food complies with the established standards.

On May 29, 2006, the MHLW introduced the positive list system for agricultural chemicals in food.* Basically, all foods distributed in the Japanese marketplace are subject to regulation based on the system.

This time the MHLW has newly established MRLs (draft) for some food commodities. Also, the MHLW has reviewed the existing MRLs. This activity is targeted to 2 chemicals: flonicamid and mandipropamid. Details are given below.

Note: The positive list system was established based on the 2003 amendment of the Food Sanitation Law. The system aims to prohibit the distribution of any food in the Japanese marketplace if it contains agricultural chemicals at amounts exceeding a certain level (0.01 ppm) specified under the Law.

Outline of revision

Flonicamid (Insecticide): This chemical is already permitted for use in Japan. The Ministry of Agriculture, Forestry and Fisheries (MAFF) will expand the scope of target crops for which the use of the chemical is permitted. Also, an application has been filed by a foreign business with the MHLW for the establishment of MRLs for the chemical, based on the Guideline for Application for Establishment and Revision of Maximum Residue Limits for Agricultural Chemicals Used outside Japan, published on 5 February 2004. In response to the MAFF's action and request by the manufacturer, the MHLW has newly established MRLs (draft) for some crops and has comprehensively reviewed the existing MRLs.

Mandipropamid (Fungicide): This chemical is not permitted for use in Japan. This time MAFF has decided to approve the chemical based on the Agricultural Chemicals Regulation Law. Also, an application has been filed by a foreign business with the MHLW for the establishment of MRLs for the chemical, based on the Guideline for Application for Establishment and Revision of Maximum Residue Limits for Agricultural Chemicals Used outside Japan, published on 5 February 2004. In response to the MAFF's action and request by the manufacturer, the MHLW has newly established MRLs (draft) for some crops. Currently, MRLs are not set for any crops.

For draft MRLs, see Attachments 1-1 through 1-2.

Establishment of Maximum Residue Limits for Veterinary Drugs (Valnemulin and Glycyrrhizic acid) in Food

Purpose and Background

The Ministry of Health, Labour and Welfare (MHLW) is going to develop the compositional specification for food. Under the provisions of Article 11, Paragraph 1 of the Food Sanitation Law, the Minister of Health, Labour, and Welfare is authorized to establish residue standards (maximum residue limits: MRLs) for pesticides, feed additives, and veterinary drugs (hereafter referred to as just "agricultural chemicals") that may remain in foods. Any food for which standards are established pursuant to the provisions is not permitted to be marketed in Japan unless such food complies with the established standards.

On May 29, 2006, the MHLW introduced the positive list system for agricultural chemicals in food.* Basically, all foods distributed in the Japanese marketplace are subject to regulation based on the system.

This time the MHLW has reviewed MRLs which had been provisionally established at the time of the introduction of the new system. Also, the MHLW has newly established MRLs (draft) for some food commodities. This activity is targeted to 2 chemicals: valnemulin and glycyrrhizic acid. Details are given below.

Note: The positive list system was established based on the 2003 amendment of the Food Sanitation Law. The system aims to prohibit the distribution of any food in the Japanese marketplace if it contains agricultural chemicals at amounts exceeding a certain level (0.01 ppm) specified under the Law.

Outline of revision

Valnemulin (antimicrobial): This chemical is permitted for use in Japan. The MHLW has reviewed MRLs which had been provisionally established at the time of the introduction of the new system.

Glycyrrhizic acid (injection for mastitis): This chemical is not permitted for use in Japan. The Ministry of Agriculture, Forestry and Fisheries (MAFF) has decided to approve some veterinary drug products whose effective ingredient is glycyrrhizic acid. In response to the MAFF's action, the MHLW has newly established MRLs (draft) for some food commodities.

For draft MRLs, see Attachments 2-1 through 2-2. The existing MRLs for valnemulin appear in the Provisional MRLs List (the Item 7, Section A "General Compositional Standards for Food," Part I "Food" in the Specifications and Standards for Food, Food Additives, Etc.). These MRLs have been modified as necessary. Finalized MRLs for these chemicals will be placed on the MRLs List in Item 6, and the MRLs currently placed in Item 7 will be deleted. The MRLs for glycyrrhizic acid will be placed in Item 6.

Attachment: 1-1

Fenitrothion (Insecticide)

Commodity	MRL (draft) ppm	Current MRL ppm
Foliage	0.3	0.3
Watercress	4.0	4
Chinese cabbage	2	
Cabbage	1	
Other cruciferous vegetables ³	4.0	4
Chicory	4.0	4
Endive	4.0	4
Spring mix	4.0	4
Lettuce (including cos lettuce and leaf lettuce)	4.0	4
Other composite vegetables ⁴	4.0	4
Welsh (including leek)	3	
Parsley	4.0	4
Celery	4.0	4
Other umbelliferous vegetables ⁵	4.0	4
Tomato	2	0.4
Pimiento (sweet pepper)	0.4	0.4
Egg plant	3	3
Other solanaceous vegetables ⁶	0.4	0.4
Cucumber (including gherkin)	1	1
Pumpkin (including squash)	0.4	0.4
Oriental pickling melon (vegetable)	0.4	0.4
Water melon	2	0.4
Melons	2	2
Makurawari melon	0.4	0.4
Other cucurbitaceous vegetables ¹⁰	0.4	0.4
Spinach	9.0	9
Other vegetables ¹²	4.0	4
Apple	1	1
Japanese pear	0.5	0.5
Pear	0.5	0.5
Quince	0.2	0.2
Loquat	0.2	0.2
Peach	1	0.7
Nectarine	1	0.6
Apicot	2	0.6
Japanese plum (including prune)	0.6	0.6
Mume plum	2	2
Cherry	0.6	0.6
Strawberry	2	3
Grape	5	
Other fruits ¹⁵	0.4	0.4

Fenitrothion (Continued)

Commodity	MRL (ppm)	Current MRL (ppm)
Cotton seeds	0.5	0.5
Tea	40	40
Hop	5	
Cattle, muscle	0.05	0.05
Sheep, muscle	0.05	0.05
Horse, muscle	0.05	0.05
Goat, muscle	0.05	0.05
Cattle, fat	0.02	0.02
Sheep, fat	0.02	0.02
Horse, fat	0.02	0.02
Goat, fat	0.02	0.02
Cattle, liver	0.08	0.08
Sheep, liver	0.06	0.06
Horse, liver	0.06	0.06
Goat, liver	0.08	0.08
Cattle, kidney	0.08	0.08
Sheep, kidney	0.06	0.06
Horse, kidney	0.06	0.06
Goat, kidney	0.08	0.08
Cattle, edible offal	0.08	0.08
Sheep, edible offal	0.06	0.06
Horse, edible offal	0.08	0.08
Goat, edible offal	0.06	0.06
Milk	0.02	0.02
Chicken, muscle	0.02	0.02
Other poultry ²⁾ , muscle	0.02	0.02
Chicken, fat	0.02	0.02
Other poultry, fat	0.02	0.02
Chicken, liver	0.02	0.02
Other poultry, liver	0.02	0.02
Chicken, kidney	0.02	0.02
Other poultry, kidney	0.02	0.02
Chicken, edible offal	0.02	0.02
Other poultry, edible offal	0.02	0.02
Chicken, eggs	0.03	0.03
Other poultry, eggs	0.03	0.03
Tomato puree	0.5	0.5
Tomato paste	2.0	2

Attachment: 1-2

Mandipropamid(Fungicide)

Commodity	MRL (draft) ppm	Current MRL ppm
Soybeans, dry	0.2	
Beans, dry ²	0.1	
Potato	0.02	
Taro	0.01	
Sweet potato	0.01	
Yam	0.01	
Other potatoes ⁴	0.01	
Chinese cabbage	2	
Cabbage	3	
Brussels sprouts	3	
Kale	20	
<i>Komatsuna</i> , Japanese mustard spinach	20	
<i>Kyona</i>	20	
Qing-geng-cai	20	
Cauliflower	3	
Broccoli	3	
Other cruciferous vegetables ⁵	20	
Endive	20	
<i>Shungiku</i>	20	
Lettuce (including cos lettuce and leaf lettuce)	20	
Other composite vegetables ⁶	20	
Onion	0.05	
Welsh (including leek)	3	
Garlic	0.05	
Other liliaceous vegetables ⁷	3	
Parsley	20	
Celery	20	
Tomato	2	
Pimiento (sweet pepper)	1.0	
Egg plant	1.0	
Other solanaceous vegetables ⁹	5.0	

Mandipropamid (Continued)

Commodity	MRL (draft) ppm	Current MRL ppm
Cucumber (including gherkin)	0.3	
Pumpkin (including squash)	0.3	
Oriental pickling melon (vegetable)	0.3	
Water melon	0.3	
Melons	0.3	
Makuwauri melon	0.3	
Other cucurbitaceous vegetables ¹⁰	0.3	
Spinach	20	
Okra	1.0	
Ginger	0.01	
Other vegetables ¹²	20	
Grape	2	
Other fruits ¹⁵	1.0	
Other herbs ¹⁹	20	

Attachment 2-1

Vanimulin (Antimicrobial)

Commodity	MRL (draft) ppm	Current MRL ppm
Pig, muscle	0.05	0.05
Pig, fat	0.05	0.05
Pig, liver	0.5	0.05
Pig, kidney	0.1	0.05
Pig, edible offal	0.05	0.05

Attachment. 2-2

Glycyrrhizic acid (Injection for mastitis)

Commodity	MRL (draft) ppm	Current MRL ppm
Cattle,muscle	1	
Cattle,fat	1	
Cattle,liver	3	
Cattle,kidney	4	
Cattle,edible offal	2	
Milk	1	

Note:

The uniform limit (0.01 ppm) will be applied to commodities for which draft MRLs are not given. Some limits in the column, "MRL (draft)," remain unchanged from the current MRLs.

1. "Other cereal grains" refers to all cereal grains, except rice (brown rice), wheat, barley, rye, corn (maize), and buckwheat.
2. "Beans (dry)" includes butter beans, cowbeans (red beans), lentil, lima beans, pegia, sultani, sultapya, and white beans.
3. "Other legumes/pulses" refers to all legumes/pulses, except soybeans (dry), beans (dry), peas, broad beans, peanuts (dry), and spices.
4. "Other potatoes" refers to all potatoes, except potato, taro, sweet potato, yam, and konjac.
5. "Other cruciferous vegetables" refers to all cruciferous vegetables, except Japanese radish roots and leaves (including radish), turnip roots and leaves, horseradish, watercress, Chinese cabbage, cabbage, brussels sprouts, kale, komatsuna (Japanese mustard spinach), kyona, qing-geng-cai, cauliflower, broccoli, and herbs.
6. "Other composite vegetables" refers to all composite vegetables, except burdock, salsify, artichoke, chicory, endive, shungiku, lettuce (including cos lettuce and leaf lettuce), and herbs.
7. "Other liliaceous vegetables" refers to all liliaceous vegetables, except onion, welsh (including leek), garlic, nira, asparagus, multiplying onion, and herbs.
8. "Other umbelliferous vegetables" refers to all umbelliferous vegetables, except carrot, parsnip, parsley, celery, mitsuba, spices, and herbs.
9. "Other solanaceous vegetables" refers to all solanaceous vegetables, except tomato, pimiento (sweet pepper), and egg plant.
10. "Other cucurbitaceous vegetables" refers to all cucurbitaceous vegetables, except cucumber (including gherkin), pumpkin (including squash), oriental pickling melon (vegetable), watermelon, melons, and makuwauri melon.
11. "Other mushrooms" refers to all mushrooms, except button mushroom, and shiitake mushroom.
12. "Other vegetables" refers to all vegetables, except potatoes, sugar beet, sugarcane, cruciferous vegetables, composite vegetables, liliaceous vegetables, umbelliferous vegetables, solanaceous vegetables, cucurbitaceous vegetables, spinach, bamboo shoots, okra, ginger, peas (with pods, immature), kidney beans (with pods, immature), green soybeans, mushrooms, spices, and herbs.
13. "Other citrus fruits" refers to all citrus fruits, except unshu orange (pulp), citrus natsudaïdai (pulp), citrus natsudaïdai (peel), citrus natsudaïdai (whole), lemon, orange (including navel orange), grapefruit, lime, and spices.
14. "Other berries" refers to all berries, except strawberry, raspberry, blackberry, blueberry, cranberry, and huckleberry.

15. "Other fruits" refers to all fruits, except citrus fruits, apple, Japanese pear, pear, quince, loquat, peach, nectarine, apricot, Japanese plum (including prune), mume plum, cherry, berries, grape, Japanese persimmon, banana, kiwifruit, papaya, avocado, pineapple, guava, mango, passion fruit, date and spices.

16. "Other oil seeds" refers to all oil seeds, except sunflower seeds, sesame seeds, safflower seeds, cotton seeds, rapeseeds and spices.

17. "Other nuts" refers to all nuts, except ginkgo nut, chestnut, pecan, almond and walnut.

18. "Other spices" refers to all spices, except horseradish, wasabi (Japanese horseradish) rhizomes, garlic, peppers chili, paprika, ginger, lemon peels, orange peels (including navel orange), yuzu (Chinese citron) peels and sesame seeds.

19. "Other herbs" refers to all herbs, except watercress, nira, parsley stems and leaves, celery stems and leaves.

20. "Other terrestrial mammals" refers to all terrestrial mammals, except cattle and pig.

21. "Other poultry" refers to all poultry, except chicken.